



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,350	08/08/2001	Soren Ebdrup	5738.204-US	3619

7590 07/15/2003

Reza Green, Esq.
Novo Nordisk of North America Inc.
Suite 6400
405 Lexington Avenue
New York, NY 10174-6401

[REDACTED] EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1624

DATE MAILED: 07/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)
	09/924,350	EBDRUP ET AL.
	Examiner	Art Unit
	Venkataraman Balasubramanian	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 and 14-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 and 14-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Applicants' response, which included amendment to claims 1, 5,18,19, and cancellation of claim 13 filed on 4/24/2003, is made of record.

Claims 1-12 and 14-23 are pending. Applicants are reminded that claims 1-12 and 14-23 will be examined to the extent they embrace elected subject matter as done in the previous office action.

In view of applicants' response, all 112 second paragraph rejections made in the previous office action have been obviated.

However, the following apply.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 19, 21 and 23 of this application. Several species embraced in the instant claim 19, 21 and 23 are not enabled in the provisional application.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

However, applicants are not granted priority to claims 19 21 and 23 for reasons said forth as above. The priority document has no enablement for the said species, composition and method of use.

Applicants' response is considered but not persuasive. Examination of the provisional application in question, earlier clearly showed that the instant application

and the provisional are not the same and that instant application has subject matter not embraced in the provisional application. Hence applicants cannot claim benefit of priority to those material not in the provisional application.

Claim Rejections - 35 USC § 102

Claims 1 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Nielsen et al. 5,889,002.

In view of applicants' amendment to claim 1 and cancellation of claim 13, this rejection has been obviated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirotte et al. 5,459,138 in view of Nielson et al. WO 97/26265 (equivalent US 5,889,002).

Pirotte et al teaches several process of making pyridinothiadiazinedioxide which include the processes a), b), c), and d) claimed in the instant claims. See column 5 through column 9. See for experimental details preparations and examples on column 11 through column 35.

Instant process claims require a thieno-fused 1,2,4-thiadiazinedioxide whereas the reference teaches pyridino-fused 1,2,4-thiadiazinedioxide.

The secondary reference Nielsen et al. WO 97/26265, teaches the equivalency of thieno-fused 1,2,4-thiadiazinedioxide with several heterocyclic ring fused thiadiazinedioxide including pyridino-fused thiadiazinedioxide. See formula I on page 3 and note the definition of A ring as well as D, B and other varible groups. Note various hetero-fused thiadiazines are enabled on pages 14-19. Also note the process on pages 21-25.

Note the starting material of the primary reference and the secondary reference are analogous and there is a clear-cut teaching in the secondary reference that the

reaction that presence of different A ring does not alter the course of the process as the reaction centers are not affected by the presence of the different A ring.

Hence, one having ordinary skill in the art at the time of the invention was made would have been motivated combine the teachings of the primary reference with the teachings of the secondary reference and employ all the process parameters taught by these prior art including the process variation permitted and expect to obtain the desired product because he would have expected the analogous starting materials behave similarly under the reaction conditions taught by these prior art. It has been held that application of an old process to an analogous material to obtain a result consistent with the teachings of the art would have been obvious to one having ordinary skill.

See also MPEP 2144.05, which says, under Optimization Within Prior Art Conditions or Through Routine Experimentation:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%). See also In re Hoeschele, 406 F.2d 1403, 160 USPQ 809

(CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

This rejection is same as made in the previous office action using Nell. Applicants appear rely on common assignee of the equivalent Nielson et al. US 5,889,002. The WIPO document applied herein would eliminate any such issue as it is published in 1997 and applicants' priority date cannot extend beyond 1999.

Applicants' traversal to overcome this rejection is not persuasive.

Applicants argue that compounds taught by Pirotte et al. are not same as instant compounds. But instant claims are process claims and the reactive centers are just the same. Applicants have not shown that variation in the core A, i.e. thieno of instant to pyridine taught by Pirotte et al. would alter the course of the reaction. Prior art of record does not support such a contention. Furthermore, applicants original claim 1 included so many variation in the A core yet was presented as viable process for all such cores. Hence applicants' argument lacks factual support.

Applicants also argue that Pirotte et al does not teach nucleophilic substitution reactions and therefore differs from instant process. Again this is not correct. On column 4-9 involves nucleophilic displacement reactions. Especially see column 9 wherein

nucleophilic substitution of Hal with amine is shown. Hence one trained in the art would be able do such displacement reactions.

Hence one trained in the art would be motivate to combine these prior art make compounds based on the combined process taught.

Hence this rejection is maintained.

Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielson et al. WO 97/26265 (equivalent US 5,889,002).

Teachings of Nielson et al., as discussed in the above 103 rejection is incorporated herein. Nielson et al. teaches several thieno-fused 12,4-thiadiazinedioxide as well as other heterocyclic ring fused thiadiazinedioxide for treating various diseases including diabetes. See formula I on page 3 and note the definition of A ring as well as D, B and other varible groups.. Note various hetero-fused thiadiazines are enabled on pages 14-19. Also note the process on pages 21-25.

Instant claims differs from Nielson et al. in claiming specific species and species which are isomeric and their composition and method of use.

However, Nielson et al. clearly teaches several isomeric thiadiazine dioxide. See pages 14-19 wherein both (2,3-e) as well as (3,2-e) thiadiazine dioxide. Hence Nielson et al. teaches equivalency of isomeric thiadiazines made with those generically claimed on page 3 for formula I. There is a clear-cut guidepost for making either of the isomeric thieno-thiadiazines. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make both the isomeric compounds variously substituted in thieno-thiadiazine ring as permitted by the reference and expect

resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 5,889,002. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the compound, composition, and method of use embraced in the instant claims are also embraced in the US 5,889,002.

Claims 18-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,329,367. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the compound, composition,

and method of use and process embraced in the instant claims are also embraced in the US 6,329,367.

These two rejections are same as made in the previous office action but are now limited compounds, composition and method of use. Applicants' argument to overcome these two rejections is not persuasive. Both the references teach thionofused-1,2,4-thiadiazine, composition and method of use which overlaps with instant claimed subject matter.

References cited in the Information Disclosure Statement (paper # 9) are made of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian

07/11/2003


BRUCK KIFLE, PH.D.
PRIMARY EXAMINER